Exhibit 6
(Filed Under Seal)

DEREK MUEHRCKE, M.D., FACS: Expert Disclosure for Debra Tinlin

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Introduction

I have been asked to review records and imaging studies and to provide a case report on Debra Tinlin who was implanted with a Bard Recovery filter that subsequently failed resulting in physical injuries to her vena cava and right ventricle. The failed filter threatens to cause future damage to her small bowel and other adjacent vital organs and structures. The Recovery filter implanted in Ms. Tinlin exhibited the following failure modes: caudal migration, tilt, fracture, perforation of the vena cava, and migration of pieces to her heart and lungs. Due to these failures, portions of the filter and fragments of it remain in her. The Recovery filter and the fractured arms in her pulmonary arteries cannot be removed percutaneously, as intended/expected by physicians and patients and as represented by Bard.

My expert opinions are based on: (1) my personal experience with IVC filters, (2) my background, education, training, and clinical experience, (3) my review and understanding of the IVC filter literature, (4) my review of Ms. Tinlin's medical records and radiology, (5) recognized and accepted principles of medicine, (6) my review of depositions previously taken in the Bard IVC filter litigation, and (7) my review of Bard's internal documents. This methodology allows me to testify regarding medical facts specific to this case and to render the opinions contained in this report.

Qualifications and Background

I am a board-certified cardiothoracic surgeon and have been practicing for the past 24 years. I attended a seven-year college-medical school curriculum at Grinnell College and Rush Presbyterian St. Luke Medical Center in Chicago, Illinois. My formal specialty training took place at Harvard Medical School and Massachusetts General Hospital, where I completed my general surgery residency and training in adult cardiothoracic surgery. I was then accepted in and completed a congenital heart surgery fellowship at Boston Children's Hospital, also at Harvard.

After completing the above-mentioned training and fellowship programs, my first position was at the Cleveland Clinic where I practiced for three years performing adult cardiac surgery. I then moved to Florida to join five former Harvard-trained cardiovascular surgeons in private practice. My current group, of which I am one of five partners, is comprised of eight heart surgeons and five vascular surgeons. We all perform cardiac, thoracic, and vascular surgery at seven hospitals in Jacksonville, Florida.

For the past 21 years, I have routinely implanted and removed (once optional filters became available) IVC filters. I have implanted and removed every iteration of Bard's retrievable filters from the Recovery filter through the Denali. I have also implanted the Cordis OptEase and TrapEase filters, the Cook Celect filter, the Greenfield filter, and the Argon Ultra filter.

My practice is equally divided between cardiac, thoracic, and vascular surgery. I perform close to 700 cases yearly. I implant approximately 20 IVC filters a year and remove approximately 25 a year. I am the Chief of Cardiothoracic surgery at Flagler Hospital in Saint Augustine, Florida. As a result of the recent litigation surrounding the use of retrievable IVC filters, I began following all of my hospital patients implanted with removable IVC filters. These included filters implanted by me, my partners, and the interventional radiologists at Flagler Hospital. This has resulted in patients being referred to me for retrieval of their optional IVC filters placed not only at Flagler Hospital but also at other institutions. A copy of my *Curriculum Vitae* has previously been produced to Defendants as part of my prior case-specific reports in the Bard IVC Filter MDL bellwether cases. An updated copy will be provided upon request.

Prior Expert Testimony

During the previous four years I testified as an expert at deposition or trial in the following cases:

1) Leo Barnes and Glenda Barnes v. Mohan Hindurpur, M.D., et al. In the 5th Judicial Court of Andrew and Buchanan County Case, 14BU-CV02619, Buchanan County, Missouri.

2) Gilbert Vought and Betsy Vought v. Joseph A. Hatdu, Delaware Bay Surgical Services; P.A. and Beebe Medical Center. In the Superior Court in the State of Delaware and in the New Castle County, C.A. No. N14C-08-195 CEB; 12/14/2015.

3) Clare Austin v. C.R. Bard, Inc., In the Circuit Court of the Seventeenth Judicial Circuit in and for Broward County Florida, case no. CACE-15-008373, Division 21.

4) Wayne D. Everitt, et al., v. University Hospital Health Systems, Inc., et al., Cuyahoga County Common Pleas, Court Case CB15846895. Deposition (03/09/2017) and trial testimony (05/12/2017).

5) Carol Kruse v. C.R. Bard Inc., In re Bard IVC Filter Product Liability Litigation, MDL No. 2641, United States District Court for the District of Arizona, case no. 2:15-md-02641-DGC. Deposition (07/24/2017).

6) Debra Mulkey v. C.R. Bard Inc., In re Bard IVC Filter Product Liability Litigation, MDL No. 2641, United States District Court for the District of Arizona, case no. 2:15-md-02641-DGC. Deposition (07/24/2017).

7) Doris Jones v. C.R. Bard Inc., In re Bard IVC Filter Product Liability Litigation, MDL No. 2641, United States District Court for the District of Arizona, case no. 2:15-md-02641-DGC. Deposition (07/24/2017) and trial testimony (04/18/2018).

8) Lisa Hyde v. C.R. Bard Inc., In re Bard IVC Filter Product Liability Litigation, MDL No. 2641, United States District Court for the District of Arizona, case no. 2:15-md-02641-DGC. Deposition (07/24/2017) and trial testimony (09/21/2018).

9) Sherr Booker v. C.R. Bard Inc., In re Bard IVC Filter Product Liability Litigation, MDL No. 2641, United States District Court for the District of Arizona, case no. 2:15-md-02641-DGC. Deposition (07/24/2017) and trial testimony (03/29/2018).

10) Consolidated cases in Maricopa County (Arizona) Superior Court: Romero v. C.R. Bard, Inc., et al., case no. CV2017-000927, Benzing v. C.R. Bard, Inc., et al., case No. CV2013-054323, Moore v. C.R. Bard, Inc., et al., case no. CV2014-008738, and Stesney v. C.R. Bard, Inc., et al., case no. CV2012-006103. Deposition (03/12/2018).

11) Bianca Fraser-Johnson and Michael Johnson v. C.R. Bard, Inc., Bard Peripheral Vascular, Inc., Christiana Care Health Services, Inc., Thomas Bauer, M.D., Cynthia Heldt, M.D., In the Superior Court of the State of Delaware C.A. No: N15C-09-207 CLS. . Deposition (04/14/2018).

12) Consolidated cases in Maricopa County (Arizona) Superior Court: Kotter v. C.R Bard., et al., Case No: CV 2017-000927, Schimpf v. C.R. Bard et al., Case No: CV 2017-000927, and Erm v. C.R. Bard et al., Case No: CV 2017-000927. Deposition (10/18/2018).

Materials Reviewed

I. Non-Case Specific Bard Materials

I have reviewed the following internal Bard documents and deposition testimony:

A. Bard Documents

1. Janet Hudnall email to David Rauch dated 2/26/04
2. Natalie Wong email to Doug Uelmen dated 5/20/04
3. Natalie Wong email to Doug Uelmen dated 5/27/04
4. Health Hazard Evaluation from David Ciavarella dated 07/17/04
5. Health Hazard Evaluation from David Ciavarella dated 12/17/04
6. G2 Perforations from Christopher Ganser dated 11/10/05
7. G2 Caudal Migrations from David Ciavarella dated 12/27/05
8. G2 Filter System - indicated for retrieval
9. G2 Filter System - Patient Questions & Answers
10. SWOT- Objective: Increase Revenue and Capture More Market Share
11. Monthly Global PV Report from John McDermott dated 2/10/06
12. Health Hazard Evaluation from David Ciavarella dated 2/15/06

13. G2 Caudal Migration Update dated 3/2/06
14. G2 Fracture Report November 2008
15. G2 and G2X Fracture Analysis dated 11/30/08
16. Bard IVC Filter Program May 2009 - Mike Randall
17. Letter from Stacy Taiber to Brent Adamson, M.D.
18. Filter Naming Memo from Bill Little dated 4/27/10
19. Eclipse 510(k) sections on changes to filter from predicate
20. Eclipse Product Performance Specification for Migration from Design History File
21. Meridian Product Performance Specification for Caudal Migration from Design History File
22. Meridian Value Proposition from Design History File
23. Meridian Commercialization Plan dated 10/1/10
24. G2 Platinum PowerPoint
25. Scott Karch Email to Dr. Thomas dated 3/6/12
26. July 13, 2015 FDA warning letter to Mr. Timothy M. Ring (BPV-17-01-00204231)
27. Instructions for Use (IFUs) for the following filters: Bard Simon Nitinol Filter, Recovery Filter, G2 Filter, G2 Express, G2x Filter, and Eclipse filter
28. Marketing brochures Recovery filter
29. Marketing brochures G2 IVC filter
30. Marketing brochures G2x IVC filter
31. Marketing brochures Eclipse IVC filter
32. Marketing brochures Meridian IVC filter
33. Marketing brochures Denali IVC filter
34. 12/21/2004 E-mail Re. "Nov Intv Rankings"
35. 7/12/2004 e-mail Re. IVC Recovery Filter Adverse Events (Migrations/Fractures) - Executive Summary
36. Recovery Filter Detached Limbs-Patient Comparison Matrix, dated 11/1/2005
37. 1/14/04 Design Review mtg minutes
38. 2/13/2004 Memo from Uelmen to Distribution Re. "Filter Migration Meeting Minutes of 2/12/2004"
39. 4/13-4/15/2004 E-mail exchange Re. "Crisis Plan and Supporting Documents for Your Review"
40. 8/3/2005 Memo Re. IVC Recovery Filter Adverse Events (Migrations/Fractures) - Executive Summary
41. 7/31/2007 PPT
42. Product Opportunity Appraisal for Recovery Filter system
43. 8/25/2004 E-mail Re. "Recovery Filter objective statement"
44. 8/26/2004 E-mail Re. "Corporate Presentations"
45. "Internal Q&A: CR Bard Recovery Vena Cava Filter",
46. 04/01/04 E-mail Re. "Recovery GI"
47. 7/15/2004 E-mail Re. "Vena Cava Filter Complications Q&A"
48. PPT "Summary of Design Modifications RNF vs G2
49. 2/26-2/27/2004 E-mail exchange Re. "Case for Caval Centering"
50. 12/11/2003 E-mail Re. "Special Design Review for Recovery - Meeting Minutes"

51. 12/9/2003 Meeting Minutes Memo from Brian Hudson Re. "Special Design Review for Recovery (Project #'s 7081 and 8008).
52. 12/12/2004 E-mail attaching 12/9/2004 Remedial Action Plan (Revised) SPA-04-12-01
53. 7/6/2004 E-mail exchange Re. "Maude Website Discussion"
54. 4/23/2004 E-mail Re. "Draft data set for statistician", BPVE-01-00510097 - 5/27/2004 E-mail Re. "Recovery Stats"
55. "Review of FDA Manufacturer and User Facility Device Experience Database (MAUDE)"
56. 4/14/2006 Memo Re. "RNF Fracture and G2 Caudal Migration update with Brian Barry"
57. Email Re G2 v. MAUDE with attachment of chart
58. Chart Filter Sales and Maude Data through Q1 2006
59. Filter Sales and Maude Data as of Q1 2004
60. 12/16/2005 E-mail Re. "Recovery Filter Limb Fractures"
61. "Failure Investigations/R002 History Review."

B. Deposition Testimony from Bard IVC Filter MDL

62. Brian Barry Deposition - 1/31/14
63. Robert Michael Carr, Jr. Deposition - 4/17/13
64. Robert Michael Carr, Jr. Deposition - 10/29/14
65. Robert Michael Carr, Jr. Deposition - 11/5/13
66. Clement J. Grassi, M.D. Deposition - 7/30/14
67. Clement J. Grassi, M.D. Deposition - 8/27/14
68. Clement J. Grassi, M.D. Deposition - 9/24/14
69. Murray Asch, M.D. Deposition- 5/2/16
70. Kay Fuller Deposition - 1/11/16
71. David Ciavarella, M.D. Deposition – 11/12/13
72. Christopher Ganser Deposition - 10/11/16
73. Janet Hudnall Deposition – 11/11/13
74. John McDermott Deposition - 2/5/14
75. Gin Shultz Deposition - 1/30/14
76. Douglas Uelmen Deposition - 10/4/14
77. Carol Vierling Deposition - 5/11/16
78. Natalie Wong Deposition - 10/18/16
79. Steven Williamson Deposition - 9/7/16
80. Medical Monitoring 30(b)(6) Deposition (John Van Vleet)-1/17/17
81. Krishna Kandarpa, MD; Deposition and exhibits– 7/19/18
82. Timothy Fischer Deposition, Mar.

II. Case-specific documents and depositions

A. Imaging Reviewed

1. 5/4/05 CTA Chest
2. 5/7/05 IVC filter placement
3. 5/8/05 CT Abdomen and Pelvis
4. 5/9/05 CT Lumbar spine
5. 5/26/05 CXR Two view
6. 6/28/05 CXR Two views
7. 10/31/05 CXR
8. 1/27/06 Thoracic spine XR
9. 1/27/06 Lumbar spine XR
10. 7/27/06 CT Chest with contrast
11. 9/26/06 CXR two views
12. 10/27/06 CT Chest with contrast.
13. 2/23/07 CXR
14. 6/11/07 CXR
15. 4/15/08 CXR
16. 4/15/08 CT Chest without contrast.
17. 2/3/12 CXR
18. 2/7/12 CT Abdomen and Pelvis with contrast.
19. 6/10/13 CXR
20. 6/10/13 CXR
21. 6/10/13 CTA Chest.
22. 6/11/13 – 6/17/13 Multiple CXR
23. 6/12/13 CXR
24. 6/14/13 CXR.
25. 7/3/13, 7/29/13, 7/30/13, 8/1/13, 8/2/13, 8/3/13 Multiple CXR single view portables.
26. 8/6/13 CXR two view.
27. 8/7/13 CT Chest without contrast.
28. 8/22/13 CXR
29. 8/22/13 CTA Chest.
30. 10/23/13 CT Chest without contrast.
31. 11/11/13 CXR
32. 11/11/13 CT Chest without contrast.
33. 3/12/14 CT Chest without contrast.
34. 8/5/14 CT Chest with contrast.
35. 8/19/15 CT Abdomen and Pelvis with contrast.
36. 12/3/15 CXR
37. 12/16/15 Clavicle XR
38. 10/18/16 CT Chest without contrast.
39. 2/26/16 Right shoulder XR

B. Medical Records:

1) Reviewed all medical records supplied from 5/7/05 to 12/16/15.
2) UW Pain Treatment 7/10/07
3) Prevea Health Centers
4) Aurora BayCare Medical Center
5) Advanced Pain Management
6) St. Vincent Hospital
7) BayCare Clinic – Cardiothoracic Surgery
8) Aurora St. Luke's Medical Center
9) Atrium Post- Acute Care of Shawano
10) Appendix A and B Aurora Medical Group

C. Depositions:

1) Mr. and Mrs. Tinlin
2) Dr. Riebe

III. Medical Literature

See list of articles attached as Appendix A.

IV. Expert Reports

I have read the expert report of Drs. Kinney, Roberts, and Kalva provided in the Bard IVC Filter MDL, and adopt and agree with the opinions set forth therein. The same is true for the exert report of Mark Eisenberg, M.D. and Dr. Kessler provided in the Bard IVC Filter Product Liability Litigation MDL.

Fees

1. My current fee for the following medical legal activities is $650.00 per hour. This includes medical records review, review of depositions, literature searches, consultation time, preparation for deposition and trial testimony, oral or written reports, all travel time (billed as portal to portal), or any miscellaneous task as requested by client.

2. My current fee for all local deposition and trial activities is $750.00 per hour. All out of area travel that requires an overnight stay is billed at $7000.00 per day. If I have to use a half day for travel or return from the location of trial or deposition, that will be billed at 3000.00 per half day. If I must cancel an entire office day to provide the requested services, an additional fee of $2000.00 per clinic/work day will be charged. Trial and out of area fees must be paid in advance of the date of travel.

Opinions

Based upon the information available to Bard at the time the filter was implanted in Debra Tinlin and at all times subsequent to the implantation of the filter, the risks of the Bard Recovery IVC filter exceeded its benefits and that this filter did not perform in a manner reasonably expected by physicians and patients, nor in the manner represented by Bard. There is no evidence in the materials I reviewed that the IVC filter implanted in Mrs. Tinlin prevented or stopped a pulmonary embolism, nor is there any evidence she suffered any further DVTs. Her filter progressively deteriorated after just three years causing her to suffer life threatening and life-injuries/altering damages as a result of the IVC filter failing to function in the fashion it was intended. Moreover, she has a nonfunctional IVC filter, she has several retained fragments of the filter which can cause future injuries, and the filter poses risk to Mrs. Tinlin but affords her no benefit at this time. The remaining Bard Recovery filter is unstable and likely to further fail and cause further potentially life-threatening problems in the future.

The purpose of this IVC filter was to prevent death and injury by trapping large clots from moving to the heart or lungs and for the device itself to remain intact, stable, within the IVC, and centered. At the time of its insertion, the filter was placed for appropriate indications and was placed properly. In using Bard's Recovery filter, physicians reasonably expected that a properly placed filter would not migrate, tilt, perforate the vena cava and adjacent organs/structures, or fracture to the degree the Bard filters (and particularly the Recovery filters) do. Because Mrs. Tinlin's filter failed in the manner to be described, Mrs. Tinlin was exposed to risks that exceeded any benefits allegedly afforded by this particular filter; additionally, no physician or patient would reasonably expect this constellation of failure modes to occur. Specifically, Mrs. Tinlin was exposed to five of the filter struts fracturing and embolizing to her heart and lungs. Two struts became stuck in her heart. She developed cardiogenic shock, anoxia/hypoxia, and multi-organ system failure as a result of the filter fragment perforating her heart and causing cardiac tamponade, requiring surgical intervention to drain a significant amount of blood that had hemorrhaged into the pericardium causing cardiac failure. She suffered hypo-perfusion to her entire body causing anoxia/hypoxia and multi-organ system failure including pulmonary dysfunction, renal dysfunction, pancreatic dysfunction, liver dysfunction, reduced oxygen to her brain, prolonged ventilation, and cardiac failure.

She required a second complex open heart surgery and vascular surgery involving her aorta with an extensive dissection of her heart muscle to extract one of two cardiac fragments as only one could be removed. Multiple incisions were made into her myocardium to extract the dangerous cardiac fragment. She required incisions on her right atrium, aorta, and left ventricle. Mrs. Tinlin suffered poor healing of her mediasternotomy incision, a ventral and diaphragmatic hernias. She has persistent chest and epigastric pain to the point she cannot lift anything weighing more than a cup of water without feeling chest pain. This is likely to be a long-term problem. As a result of her prolonged intubation she has suffered tracheomalacia causing her to her constant shortness of breath, coughing fits, pooling of tracheal secretions, and difficulty breathing which will be life-long problems for her.

She required a third surgery to repair a diaphragmatic and epigastric hernia as a result of her IVC filter surgery, which compromises her respiratory function. A surgical mesh was

required to replace a portion of her injured diaphragm producing a non-functional area of the diaphragm which is contributing to her shortness of breath. These problems are well known complications of open-heart surgery and are directly a result of her IVC filter fragments embolizing to her heart. They are also likely to be long-term problems.

Mrs. Tinlin's post open heart problems will require life-long follow up. It is very likely her tracheomalacia, respiratory compromise/dysfunction, and shortness of breath will progress. She is now at risk for cardiac arrhythmias, cardiac failure and recurrent diaphragm hernias, and she has anxiety about her diaphragm hernia recurring. She will require semi-annual surveillance from a pulmonologist to monitor her shortness of breath from the tracheomalacia and diaphragm injuries. She will require semi-annual cardiology and cardiac surgery follow ups with chest CT scans, echocardiograms, and EKGs to monitor for persistent sternal non-union, arrhythmias, endocarditis, and cardiac dysfunction as a result of the multiple incisions made into her heart during the unconventional open-heart retrieval of her IVC filter fragment. Moreover, Mrs. Tinlin has three more filter struts which have embolized to her lungs. Recent articles in the literature (Kesselman 2018, Trerotola 2017) following pulmonary and cardiac fragments which have embolized suggest early evidence that these fragments may be followed closely clinically with little consequences. Nonetheless, these studies suffer from short follow up and inadequate follow up of their patients. Mrs. Tinlin suffered her first fragment embolization to her heart five years after her Bard Recovery IVC filter was placed. Five years later (10 years after her filter implantation) that fragment perforated her heart causing cardiac tamponade and multi-organ system failure. Clearly reports in the literature with only two years of follow up are inadequate to suggest retain IVC filter fragments can be safely watched. Moreover, pulmonary fragments are known to cause bleeding, hemoptysis, pneumothorax, and death.

Unfortunately, Mrs. Tinlin still has a Recovery IVC filter which has only seven of its twelve struts intact. This imperfect filter needs to be removed and replaced with a more reliable IVC filter. Her current IVC filter has essentially no clot stopping ability as a result of several of its clot catching struts being missing and is unstable. Moreover, an additional strut can embolize at any time to her heart causing her to suffer cardiac tamponade and multi-organ failure again. This filter will require a complex attempt at endovascular removal at a center which specializes in complex filter removals; such as by Dr. Kuo at Stanford Medical Center. If it cannot be removed percutaneously then open removal will be required. A new IVC filter will be required. Had a Simon Nitinol Filter been placed originally these problems would have likely not occurred. Currently a Vena Tech filter should be placed into her IVC as she will require life-long protection form pulmonary embolisms given her difficulty modulating her Coumadin, and her thrombophilia. Mrs. Tinlin has suffered chronic renal failure, exacerbation of her diabetes, and multiple respiratory difficulties as a result of the damage done by the Bard Recovery filter. She has suffered significant chest and back pain from her failed Bard Recovery filter.
At the time Mrs. Tinlin's Bard Recovery filter was implanted, Bard was well aware its retrievable IVC filter had a death rate, fracture rate, migration rate, and perforation rate four to five times its competitors. Yet it continued to sell the defective filter. Bard failed to reveal the contents of their internal studies and analysis of the Bard Recovery filter to implanting physicians and patients. This information was necessary to give informed consent to patients and to understand the performance long term of these filters. This information is something implanting physicians and patients would have wanted to know.

Moreover, Bard failed to warn implanting physicians of these problems, thus preventing physicians from giving accurate and adequate informed consent when placing these filters. Had I been aware of the greater risk of death, fracture, migration, and tilt associated with the Bard filters, I would not have used the filter. More likely than not, most reasonable surgeons would not have used the filter either.

I have been involved with the development of videos to be used to demonstrate how Mrs. Tinlin's Bard Recovery filter failed and how its failure produced life threatening cardiac tamponade. Moreover, the videos will demonstrate the life-long problems Mrs. Tinlin will suffer as a result of her defective IVC filter as well as the risk associated with the disintegrating IVC filter and retained pulmonary filter fragments.

At the time of this report, certain of Mrs. Tinlin's treating physicians are scheduled to be deposed but have not yet been deposed. I intend to review the transcripts of those depositions and may testify to the facts contained in those depositions to the extent that they relate to my opinions as set forth in this report.

My opinions are based on the reasonable expectations that he and other similarly situated physicians have in regards to the responsibilities of a medical device manufacturer for the design, marketing, sales, and performance of their medical devices.

Future Recommendations

1) Attempt percutaneous removal of four intrapulmonary fragments.

2) If unsuccessful, then chest CT scan monitoring semi-annual by a pulmonologist.

3) Percutaneous removal of IVC filter as it is non-functional and creates a risk for DVT and PE.

4) If it cannot be removed, then consideration for open removal as it is non-functional and a source of potential future heart/lung fragments.

5) Yearly CT scan of the abdomen to monitor the IVC filter for further deterioration and interaction with surrounding vascular structures.

6) Yearly follow up with a cardiac surgeon to monitor her pulmonary filter fragments, her sternal wound, diaphragm hernia, tracheomalacia, and right clavicular hear injury.

7) Yearly cardiology EKG and follow-up to monitor her heart rhythm and cardiac function.

8) Twice yearly follow up with her primary care physician to follow her chronic renal dysfunction, pancreatic function, liver function, mental status, and shortness of breath.

9) Placement of a new permanent IVC filter to protect her from pulmonary emboli due to her thrombophilia, and difficulty tolerating Coumadin therapy.

My opinions are based on his review of scientific and medical literature Bard internal documents, depositions, expert reports, and his clinical experience, education, and training. I did my own medical literature research and review, as well as reviewing literature provided to me by Plaintiff's counsel. It is anticipated that I will show video material and/or cartoon representations at the time of trial for illustrative purposes to help educate the jury on how Mrs. Tinlin's IVC filter was placed, how it deteriorated within her, and the subsequent damages the IVC filter caused to her.

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Bard Recovery Filter Specific Opinions

I reviewed relevant Bard documents to assess whether prior to May 7, 2005, physicians, including Dr. Riebe, was provided with information that doctors who choose and implant IVC filters would expect and require to perform an accurate risk/benefit analysis, provide appropriate informed consent, and determine when to remove the Recovery filter, considering the design and safety issues Bard knew or should have known about. C.R. Bard had early warnings that their Recovery filter had problems with migration and fracturing. The Asch study, done as a short-term retrieval study only, demonstrated one migration in the first 11 patients (9%). Dr. Asch's 2002 radiology study can be summarized as follows: There were two (2) tilted filters, one (1) migration with trapped thrombus and one (1) asymptomatic caval perforations or four (4) complications or 12.5 %. This should have prompted Bard to revisit the design features of Recovery filter and to initiate a safety and effectiveness clinical trial to gain knowledge about the long-term safety and effectiveness of the Recovery filter, especially if Bard's plan was to market the Recovery filter as an optional retrievable and permanent device. According to Dr. Asch's deposition, Bard promised it would do both before releasing the Recovery filter into the marketplace, i.e., make appropriate design changes and conduct a long-term safety and effectiveness clinical trial. *See* Murray Asch, M.D. Deposition Transcript, May 2, 2016 (43:10-46:24; 117:6-199:16).

Not reported in Dr. Asch's study was a fracture of the Recovery filter which occurred in patient number 33 (one patient after the original Asch series of 32 patients). Deposition of Murray Asch, M.D., May 2, 2016. In Dr. Asch's May 2, 2016, deposition, he emphasizes that his study specifically focused on safety of retrievability while also studying filter performance and complications during the expected short-term indwell time of the Recovery filter. A long-term study of the Recovery filter, he recognized was important and necessary, and needed to be structured in a different manner than the study he conducted; that is a study with a substantially larger patient population (a hundred or even a thousand) to study the safety of the Recovery filter rather than a small retrieval study. Bard even informed Dr. Asch that it planned to perform such a study before deciding to launch this new IVCF, and before it submitted the Recovery filter

510(k) application for clearance by the FDA. Deposition of Murray Asch, M.D., May 2, 2016 (19:2 -20:17).

Despite Dr. Asch's belief, in June 2002, NMT/Bard used his study to justify launching the Recovery filter for widespread U.S. marketing and obtained 510(k) FDA clearance based on Dr. Asch's Recovery filter paper from Radiology, and comparing the device to the Bard SNF, Meditech (Boston/Scientific), and Titanium Greenfield as predicate devices. Dr. Asch expressed his concern to NMT/Bard that the release of the Recovery filter should not be effective until a clinical study for safety and efficacy, not solely retrievability, was completed. Again, he was reassured that NMT/Bard would perform a large multicenter prospective American study to assess long-term performance of the Recovery filter. No such study was ever done by Bard.

Bard had warnings before May 7, 2005, that Recovery filters were migrating and causing deaths. There was concern among thought leaders in the field that ease of retrievability might also result in higher rates of migration than was seen with the more extensive experience with permanent filters. From March 24-30, 2004, the annual Society of Interventional Radiology (SIR) Meeting was held in Phoenix Arizona. Dr. Kinney moderated a session on IVC filters including retrievable filters with much enthusiasm raised about the ability to retrieve filters at a much longer filter in-dwell time compared to the Gunther Tulip or temporary filters alluded to above. The newer filters could be removed when the risk of DVT/PE had resolved and/or the patient had recovered completely. At the conference, Dr. Kinney raised a concern that ease of retrievability might also result in higher rates of migration than was seen with the more extensive experience with permanent filters. Shortly after the session presented by Dr. Kinney, Bard hosted an animal training session to train physicians on insertion and retrieval of the Recovery Filter; of note, Bard did not share any of its findings on the Recovery filters design defects.

A former Interventional Radiology fellow at UCSD, Dr. Alex Powell, experienced a fatal migration of an RNF in an obese patient, within weeks after the March 2004 SIR meeting. The filter had been in place a relatively short period of time and the patient went into the bathroom to relieve himself and died. The assessment was embolic insult of the RNF in an obese patient. However, prior to Dr. Powell's experience, Bard's internal documents demonstrate that there were multiple instances of significant complications with the RNF.

On October 17, 2003 Bard received its first migration complaint from the field. On November, 29, 2003, Bard received a second complaint of migration. In December, 2003, Bard received a report of a detached limb. On February 9, 2004, Bard received its first complaint about migration with patient death. On February 10, 2004, the BPV Management Board (Division PAT) met to discuss the Recovery filter complaints and to assign resources to "aggressively complete" an investigation, and by February 12, 2004, Bard's Division and Corporate PAT met to develop a remedial action plan. On March 4, 2004, Bard's Division and Corporate PAT team met to discuss all information per the remedial action plan. On March 10, 2004, Dr. John Lehmann submitted a Recovery Filter Migration Health Hazard Evaluation. This HHE concluded that "[t]he evidence to date does not suggest these types of events (migration) are occurring with excess frequency" with the Bard Recovery Nitinol Vena Cava Filter. On April 14, 2004, Bard received a second complaint from the field about a migration of the Recovery filter and patient death. On April 14, 2004, the Recovery filter product was placed on

"QA Hold" pending a completion of the remedial action plan. On April 21, 2004, Bard's Division PAT committee met to discuss all information obtained per the remedial action plan. On April 24, 2004, Bard's Christopher Ganser indicated (after discussion with Dr. John Lehmann) the remedial action plan after the second patient death would not differ from the HHE from the first patient death: "the evidence to date does not suggest these types of events are occurring with excess frequency with the Bard Recovery IVC." So, on April 27, 2004, the QA Hold was lifted by Dr. John Lehmann. (BPVEFILTER-01-00003802-836 at 816).

By the end April 2004, the BPV/Angiomed New Product Development Review Meeting presentation stated in light of complications associated with RNF, including fractures and tilting, "a consistent mechanism of filter fracturing to date", "removal difficulties: where the cone has proven to be user dependent and requires extensive training", and "R002 migration"- Bard began developing a "plan to address filter migration" by developing a new product called G2, with an earlier phase called G1A. Many different design changes were considered such as greater pressure resistance in their migration testing (> 80mmHg@ 28 mm), hook strength sufficient to provide migration resistance but be removed atraumatically, different hook wire diameters and filter leg diameters. Another animal study was planned to study vessel injury and healing after retrieval. The release of the new filter was not anticipated until December 2005. (Slide 21 of the BPV/Angiomed presentation; Kessler Report, Pg. 59, para. 171).

On May 20, 2004, Bard received statistical data analysis from Natalie Wong that showed a 95% confidence level there was a significant difference between RNF and the Gunther Tulip, Birds Nest, and Simon Nitinol Filter relating to the most significant clinical outcome: death. (Kessler Report, pg. 59 para. 173).

It is my opinion that this information was important for physicians to know in making decisions to use the Recovery filter and would have impacted the decision-making of a reasonable physician as of May 7, 2005. As of this date, the data raises safety concerns about the stability of Recovery filter. As a physician whose patients look for appropriate health and treatment advice, expect that with these statistically significant finding of increased fatalities, Bard would immediately recall and stop selling the Recovery Filter. (BPVE-01-00511127).

It is the velocity of reported complications and not merely the percentage that causes concern. For instance, 25 filters migrated after 15,000 potential implants. Within 6-9 months of filter use, fractures and filter embolizations were occurring and likely to continue or even accelerate into the future. At this point in time, there was a large pool of patients at risk for potential life-threatening complications, and Bard continued to place patients at unacceptable levels of risk. As later clinical studies eventually showed, the filter complications of the RNF and G2 continuously increased with longer time-periods of indwell.

Between April 2004 and December 2004, there were seven (7) additional migration deaths (April 13, 2004; May 8, 2004; May 30, 2004; July 24, 2004; August 16, 2004; November 15, 2004; November 28, 2004). (BPV-17-01-00035618). The Bard Remedial Action Plan (RAP) dated January 4, 2005, stated: "In the MAUDE dataset, the RNF demonstrated a consistent statistically significant and potentially clinically important higher rate of report of adverse events in several analyzed categories. Of greatest concern were reports of migration and fracture….

Given the pattern of reported events, a higher rate of death reports seems related to fracture movement and filter embolization….” Later in the same RAP, “Linear regression analysis showed a significant inverse correlation of reported migration rates to the migration resistance values in the bench testing.” suggesting that (Ref. Lehmann Report P21/21):

a. Bench testing may be predictive for clinical performance

b. The two independent datasets (MAUDE report rates and bench results) contain significant signals regarding vena cava filter performance related to migration.” (BPVE-01-01019773).

This acknowledges high filter migration rate values. It is my opinion this confirmed the concerns of Dr. Kinney that the design parameters emphasized retrieval at the expense of migration/embolization risk.

Despite these warning indicators, the RNF was sold until introduction of the G2 in September 2005.

Clearly these design issues related to migration and fracture of the Recovery filter. The RNF brokered new, unknown ground in regards to retrievability. In my opinion, the design focused too much on making features to facilitate ease of retrieval (i.e. low forces) - smaller wire sizes, ground-down hooks, smaller diameters in the upper and lower filtering segments, rounded hook design in RNF compared to Simon Nitinol, and also lower number of elements (7 arches in upper filter element of Simon Nitinol versus 6 in RNF). But, ease of retrieval has a design tradeoff: ease of migration and possible embolization. The reduction in wire sizes, manufacturing issues, and uncertain loading conditions created potential physical stresses on the filters or parts of filters perhaps pre-disposing filters to fracturing, migrating, tilting, perforating and embolizing with serious potential consequences. Filters with loss of components can have even greater stresses, exposing them to greater loads and compromised filtered efficacy as mentioned above.

In my opinion, and consistent with Dr. Kinney’s advice to Bard as a consultant, the expectations of members of SIR, and other physicians who order and implant IVC filters from the standpoint of stability and strength, safety, and effectiveness, risk and benefit, should not be compromised in making an IVC filter retrievable, especially if the device was also indicated for permanent placement. As Rob Carr, Vice President of Engineering, stated in his deposition (April 17, 2013, 32:10-23) the Bard retrievable devices are first and foremost permanent devices.

Moreover, Bard represented and marketed their devices as new, improved and taking strength and stability to a new level. Never was there a communication from Bard, nor was any data of internal analyses shared with physicians which would indicate any Bard IVC filter had design defects or features that statistically significantly increased the risk of known potential complications, including the very rare risk of death from embolization of the entire filter when challenged by clot(s), perforations, thrombi or the embolization of broken pieces of metal to other organs. Bard’s sales representative Timothy Fischer testified that, as a sales representative, he was not aware of the internally available statistics at Bard regarding Recovery’s failure rates

and incidence of migration, fracture, and death and that, if he had been aware, he would have wanted to provide that information to physicians. Deposition of Timothy Fischer, dated Mar. 29, 2017, at 111:15-112:13, 166:4-12, 168:12-169:1, 216:24-218:8, 224:19-225:3, 281:13-282:10. Likewise, implanting physicians would have wanted to know that information in order to make informed decisions as to whether to use the Recovery filter and, if so, for how long they would have allowed the Recovery filter to remain implanted in their patients. Bard's failure to provide that information to implanting doctors denied them important information in making informed decisions about treatment and obtaining informed consent from patients as to that treatment.

My opinions are to a reasonable degree of radiological certainty. Plaintiff reserves the right to supplement my opinions consistent with further discovery including depositions of the parties and other witnesses and his review of Plaintiff's medical records and imaging. Further, Plaintiff anticipates that I will address and/or rebut opinions of Defendants and experts identified by Defendants.

Attached at Appendix B are demonstrative exhibits that I may use at trial to assist in presenting my testimony to the jury.